

a¹

--To facilitate retention of the dosage forms of the invention, particularly if the dosage form is to be administered to a subject in the fasted state, it may be desirable to combine one or more gastric-emptying delaying agents with the active agent composition or coat the dosage form with a composition containing a gastric-emptying delaying agent, i.e., a substance that delays onset of the housekeeping wave of the IMMC. Examples of agents for delaying onset of the housekeeping wave, preferably locally delivered by the dosage form in amounts not resulting in any substantial systemic effect to the subject, as for example, anticholinergic agents such as propantheline, and other agents including, but not limited to, methylcellulose, guar gum, fats such as triglyceride esters, e.g., triethanol myristate, fatty acids of 10-15 carbon atoms, and the like.--

Please replace the paragraph beginning on page 43, line 14 with the following rewritten paragraph:

a²

--The active agent dosage form may include additional ingredients, such as, for example, a buffer or other agents for controlling pH in the stomach or elsewhere in the gastrointestinal tract, an agent or agents for delaying onset of the housekeeping wave, preferably locally delivered by the dosage form in amounts not resulting in any substantial systemic effect to the subject, as for example, anticholinergic agents such as propantheline, and other agents including, but not limited to, methylcellulose, guar gum, fats such as triglyceride esters, e.g., triethanol myristate, fatty acids of 10-15 carbon atoms, and the like, a viscosity regulating vehicle, a surfactant, a dye, a permeation enhancer, a proteinase inhibitor, or other formulation ingredients and additives, as are known in the art. The active agent dosage form may also include minor amounts of polymers which serve useful functions in tablet formation, for example, to improve the tablet cohesiveness after compression or to improve the physical or chemical stability of the dosage form. These polymers are added at quantities less than 10% by weight and preferably less than 5% by weight of the tablet. Examples of such polymers include hydroxypropyl methyl cellulose having molecular weights of less than 20,000 grams per mole, methylcellulose having a molecular weight of less than 20,000 grams per mole, polyvinyl pyrrolidone having a molecular weight of less than 360,000 grams per mole, and the like.--

Please replace the paragraph beginning on page 57, line 9 with the following replacement paragraph:

a³ -- The present invention is described and characterized by one or more of the following technical features and/or characteristics, either alone or in combination with one or more of the other features and characteristics: an active agent dosage form adapted for gastric retention comprising: (a) a first layer comprising a swellable, water-soluble polymer; (b) a second layer comprising a therapeutically-effective amount of an active agent, the second layer being laminated with the first layer at a common surface, and (c) at least one band of insoluble material circumscribing and binding together the first layer and the second layer, the first layer being adapted to swell in the stomach to facilitate retention of the dosage form in the stomach over a prolonged period of time, wherein the release of the active agent from the second layer is independent of the composition of the first layer and occurs over a prolonged period of time; a dosage form wherein the number average molecular weight of the water-soluble polymer is between about 100,000 and 20,000,000 grams per mole; a dosage form wherein the water soluble polymer is polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, sodium carboxy methylcellulose, calcium carboxymethyl cellulose, methyl cellulose, polyacrylic acid, maltodextrin, pre-gelatinized starch, guar gum, sodium alginate, or polyvinyl alcohol; a dosage form wherein the second layer comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked Amberlite resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules and sodium carboxymethyl starch, and the first layer optionally comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked Amberlite resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules and sodium carboxymethyl starch; a dosage form wherein the first layer swells more rapidly and to a greater extent than does the second layer; a dosage form wherein the active agent

is. an antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent; a dosage form wherein the weight percent of the water soluble polymer in the second layer is 5 to 99.99 weight percent and weight percent of the hydroattractant in the second layer is 0 to 60 weight percent; a dosage form wherein the prolonged time period is at least 3 hours; a dosage form wherein the prolonged time period is between about 6 to 12 hours; a dosage form wherein the first layer comprises polyethylene oxide having a number average molecular weight of at least 100,000 grams per mole; a dosage form wherein the active agent is acyclovir, ganciclovir, ritonavir, minocycline, cimetidine, ranitidine, captopril, methyldopa, selegiline, minocycline, fexofenadine, metformin, bupropion, orlistat or a pharmaceutically acceptable salt thereof; a dosage form wherein the second layer comprises an active agent selected from the group consisting of acyclovir, ganciclovir, ritonavir, metformin, bupropion, orlistat and minocycline, and the second layer comprises a bioerodible polymer, a therapeutically effective amount of the active agent being delivered to the stomach of a subject over at least a 3 hour period; a method of treating a subject in need thereof with an active agent that comprises administering to the subject a multilayered dosage form adapted to be retained in the stomach over a prolonged period of time, the dosage form comprising a second layer adapted to swell in the stomach of the subject and retain the dosage form in the stomach for a prolonged period of time, and a first layer adapted to deliver to the subject an active agent at a variable rate of delivery; a method which comprises administering one or more dosage forms to the subject in the fed state at the start of each dosing period; a method wherein the administration of the dosage form occurs within one hour of the subject consuming food; a dosage form comprising a gastric-emptying delaying agent; a dosage form wherein the gastric-emptying delaying agent is selected from anticholinergic agents, methylcellulose, guar gum, fats and fatty acids of 10-15 carbon atoms; a dosage form wherein the active agent comprises a liquid, active agent formulation; a dosage form wherein the liquid, active agent formulation is sorbed into porous particles; a dosage form wherein the porous particles are calcium hydrogen phosphate or magnesium aluminometasilicate; a dosage form comprising a pH regulating agent or a chelating agent; a dosage form wherein the liquid, active agent formulation comprises a pH regulating

a3
cont